

Exhibit A

IN THE CIRCUIT COURT OF
THE SEVENTEENTH JUDICIAL CIRCUIT, IN
AND FOR BROWARD COUNTY, FLORIDA

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CLARE AUSTIN,)	Case No.
)	
Plaintiff,)	CACE-15-008373
)	
v.)	
)	
C.R. BARD, INC., a foreign)	
corporation and BARD)	
PERIPHERAL VASCULAR, INC.,)	
an Arizona corporation,)	
)	
Defendants.)	

-----x

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VIDEOTAPED DEPOSITION OF KRISHNA KANDARPA, M.D.

BETHESDA, MARYLAND

THURSDAY, JULY 19, 2018

12:57 P.M.

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Reported by: Leslie A. Todd

1 A Correct. Yes, I am.

2 Q And what does that mean in the context
3 of an IVC filter?

4 A Okay. That is -- you've got to get this
5 filter that's obviously much larger than the
6 vessel you're trying to put it in through. The
7 femoral vein, for example, may be, depending on
8 the patient and the hydration status, may be
9 somewhere around 8 to 10 millimeters. So you
10 usually use a needle to enter the vein, and then
11 you put a sheath which will carry your collapsed
12 filter. Then you introduce your sheath to the
13 point where you think the filter will land. So
14 once you do that, you pull back on the sheath, and
15 the filter will open its legs and the cone will
16 sit where it's supposed. That is called a
17 deployment. Now you've deployed that filter where
18 you want it.

19 Q All right. And as the medical monitor,
20 did you have an expectation that when the G2
21 filter was deployed as part of this study that it
22 would be centered within the vena cava?

23 MR. NORTH: Objection to the form.

24 THE WITNESS: That's the expectation.

1 BY MR. JOHNSON:

2 Q Yes.

3 A That's the expectation, absolutely.

4 Q Did you have an expectation that when
5 the G2 filter was deployed during the study that
6 it would remain in place, remain stable?

7 MR. NORTH: Objection to the form.

8 THE WITNESS: That -- that's what --
9 usually what we want out of any filter, because
10 it's predictability. You know, we don't -- we
11 don't want the filter moving away to the lungs and
12 things like that.

13 BY MR. JOHNSON:

14 Q Okay. What about moving downward?

15 A Well, we don't want it to move at all
16 actually. I think one of the things about these
17 structures you put in is the stability and the --
18 I can go home and sleep at night thinking it's not
19 going anywhere, you know.

20 Q All right. Now, you mentioned just a
21 second ago something about the hydration of the
22 patient relating to the inferior vena cava.

23 A Right.

24 Q Explain what you meant by that.

1 it in the right spot, the renal veins will slowly
2 dissolve them. You know, blood from the renal
3 veins will slowly dissolve them.

4 So that's -- that's what I mean by clot
5 trapping. I mean they are made to trap clots,
6 especially the big ones.

7 Q All right. And are you familiar with
8 the term "filter migration"?

9 A Yeah.

10 Q All right. And what does that mean in
11 the context of an IVC filter?

12 A Well, it -- it could mean -- it means
13 that the filter has moved from the original spot
14 you -- you put it in. It -- I suppose you
15 could -- you say, I intended to put it here, but
16 it went and sat somewhere else. So that would be
17 filter migration.

18 Q All right. And I think you mentioned
19 this a second ago, but you talked about strength
20 and stability of the filter as it relates to
21 migration of the filter. Explain what you meant
22 by that.

23 A Okay. What I meant was the
24 understanding that the structure of the filter

1 once deployed is now -- is integral to where it's
2 lying so that it's strong enough to stay there
3 and -- and nothing happens to it. So -- so the
4 design of the filter is important in its ability
5 to be stable at a location.

6 Q Right. I'm going to put Exhibit 3 back
7 up on the ELMO.

8 A Okay.

9 Q And hopefully -- let me see if we turn
10 this light off if that helps.

11 A Is it 3 or 4?

12 Q I'm sorry, 3.

13 A Three -- is it 3? Okay.

14 Q I'm sorry. I don't know if that is any
15 better or not.

16 In any event, does this illustration
17 show an IVC filter properly in place and centered
18 within the vena cava?

19 A I would say that it's acceptable. As I
20 said again, it looks like it's a retrieval. It's
21 got a hook. I would like to see it a little
22 higher because -- because -- but, yeah, I mean
23 it's acceptable, it will do its job, but it's not
24 optimal.

1 of the filters can go right through the heart
2 because the right atrium, the wall is very thin.
3 I've seen this happen, and it's not a good thing
4 to have a hole in your heart.

5 Q All right. You also mentioned something
6 about the filter moving downward or in a cephalic
7 direction.

8 A Mm-hmm. A caudal.

9 Q Caudal.

10 A It's downward.

11 Q Oh, I'm sorry. Why do you not want that
12 to happen?

13 A Well, because it reflects instability.
14 Yeah, I mean, it -- you know, it sort of saying,
15 Well, look, you don't want it moving down. And
16 the other thing is very seldom do we want it
17 moving into the iliac veins because that means the
18 legs are crushed down much further than they would
19 be in the IVC. There are times when you put it
20 there because you don't have a choice, but you
21 wouldn't -- you wouldn't want your filter that you
22 put in the IVC to move into the iliac veins.

23 Q All right.

24 A Or any further down, yeah.

1 Or any further down from where it was,
2 yeah.

3 BY MR. JOHNSON:

4 Q All right. Filter tilt, what does that
5 mean?

6 MR. NORTH: Objection to the form.
7 Seeks expert opinion.

8 BY MR. JOHNSON:

9 Q Doctor, as part of your role in this
10 case as the medical monitor, were you evaluating
11 this filter as it relates to tilt?

12 A Yes, I was.

13 Q Okay. What does "filter tilt" mean?

14 A Okay. Well, the implications of filter
15 tilt, if you look at a filter that's deployed
16 properly and you look at it head on within the
17 interior vena cava, you know, a cross-section if
18 you will, you will see that a certain -- there is
19 a certain area that is restricting the clots.
20 What happens when the filter tilts is that those
21 areas increase -- I mean there are studies on
22 this -- and so larger clots can go through.

23 And in its extreme, it could -- it's
24 not doing -- it's not functioning at all, and --

1 the things obviously that we look for and made
2 sure that there wasn't an undue amount of that.

3 BY MR. JOHNSON:

4 Q Did you form a belief as the medical
5 monitor that there was an association between
6 filter migration, filter tilt, and perforation of
7 the filter through the vena cava?

8 MR. NORTH: Objection to the form.

9 THE WITNESS: I didn't form -- I didn't
10 form that opinion because of the study. It's
11 something that happens that's generally known that
12 you don't want that because these are the
13 consequences of a migrating filter. Okay. So
14 I -- I consciously probably didn't say it, but I
15 sort of understood that that was what was going
16 on.

17 BY MR. JOHNSON:

18 Q Okay. Did you -- are you saying you
19 understood that was going on with the G2 filter?

20 A Yes.

21 MR. NORTH: Objection to the form.

22 THE WITNESS: In the study, yes.

23 BY MR. JOHNSON:

24 Q Okay. This retrievability study, was it

1 perforation of the filter through the inferior
2 vena cava?

3 A Yes.

4 MR. NORTH: Objection to the form.

5 THE WITNESS: Yes.

6 BY MR. JOHNSON:

7 Q All right. I'm not going to continue
8 going through this document.

9 A Okay.

10 Q But based on your work as the medical
11 monitor in this case, based upon your device
12 observations and adverse events that you were
13 responsible to adjudicate, did you form a belief
14 that there was a stability problem with the G2
15 filter?

16 MR. NORTH: Objection to the form.

17 THE WITNESS: Yeah. Yes, I think when
18 you look at the totality of all the findings and
19 you try to relate them, that you -- you would
20 think that it stems primarily from the stability
21 of filter position once deployed.

22 MR. JOHNSON: Okay. What's our next
23 exhibit? I don't want to make -- continue making
24 a mistake.

1 Q What -- what does the migration rate
2 that you were aware of as the medical monitor
3 indicate to you regarding the strength and
4 stability of the G2 filter?

5 MR. NORTH: Objection to the form.

6 THE WITNESS: I -- I could tell you
7 that -- that it -- that it's suffering from an
8 ability to be placed stably. Once you lose that
9 ability, you can move and you can be positioned in
10 ways with the inferior vena cava where you're
11 subjected to forces, you know, like the pulsations
12 and everything else, that struts might not have
13 been designed for, so you're then predisposed to
14 fatigue fractures and all the rest of it. So it's
15 not something that I would take lightly.

16 BY MR. JOHNSON:

17 Q All right. As the medical monitor, did
18 you form a belief that the migration rate that you
19 observed was high?

20 A Yes.

21 MR. NORTH: Objection to the form.

22 BY MR. JOHNSON:

23 Q What -- what that was belief?

24 A I believed that the migration rate was

1 higher than -- than in my experience.

2 Q Were there definite cranial migrations
3 or upwards migrations of the G2 filter that you
4 observed as the medical monitor?

5 MR. NORTH: Objection to the form.

6 THE WITNESS: I cannot remember
7 individual ones, but clearly it's recorded and I
8 must have seen them.

9 BY MR. JOHNSON:

10 Q Do you have a recollection of there
11 being upward or cranial migrations of the G2
12 filter that were observed by you?

13 A Yeah, probably. Yeah -- I mean as I
14 said again, I mean I can't remember individual
15 ones, especially the one that says 5 millimeters
16 upward cranial, you know, I mean I remember that,
17 but anything that's big in terms of anything more
18 than 1 centimeter, you know, that would be
19 something that we would have talked about.

20 Q Go ahead.

21 A No. Yeah -- so, yeah, obviously I saw
22 it. I don't -- given 12 years, I don't remember
23 individual cases.

24 Q With respect to the migration rate that

1 looks like it might could use a redesign.

2 Q All right.

3 A Yeah.

4 Q Looking back on the device observations,
5 looking back on the adverse events, you've made it
6 clear that it was not within your power to either
7 stop this study or to initiate a process to stop
8 this study.

9 A Mm-hmm.

10 Q If you had that ability, would you have
11 done so?

12 MR. NORTH: Objection to the form.

13 THE WITNESS: Yes. Yeah. If I had the
14 ability, and I was told, you know, you are
15 responsible for letting people know about these
16 issues, other than through the channels through
17 BBA, yeah -- and if I had responsibility for that,
18 definitely. Yeah.

19 BY MR. JOHNSON:

20 Q Doctor, you've spoken to us about caudal
21 migration, and that is downward migration, as well
22 as upward migration, and I believe we've
23 established that you were involved in this adverse
24 event adjudication and device observation

1 Q Yes.

2 A Yeah, it would be. Yeah.

3 Q And when a IVC filter is being
4 represented as having improved centering, what
5 does that mean to you?

6 A I just -- that means that when I'm
7 deploying it, that chances are high that it will
8 stay with the cone in the middle of the lumen.
9 That's what it -- that's what the message is,
10 improved centering. That it's not going to tilt,
11 it's not going to -- it's going to stay there
12 where I want it to be with the maximum filtration
13 faced towards the flow.

14 Q Was that something that you
15 experienced -- was that the case with the G2
16 filter in the EVEREST Study, that it had improved
17 centering over other devices on the market?

18 A Well, not when -- well, you can't
19 conclude that. You can't conclude that given --
20 given the fact that there were so many tilts and
21 migrations.

22 Q Now, did you know, Doctor, that in June
23 of 2006 when you were involved in the study, that
24 Bard also met with some of your colleagues and had

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17

18 LESLIE A. TODD, CSR, RPR

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